



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. FDA-2014-D-1584]

Same Surgical Procedure Exception: Questions and Answers Regarding the Scope of the Exception; Draft Guidance for Industry; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the draft document entitled “Same Surgical Procedure Exception: Questions and Answers Regarding the Scope of the Exception; Draft Guidance for Industry” announced in the Federal Register of October 23, 2014. FDA is reopening the comment period to allow interested persons additional time to submit comments and any new information.

DATES: Submit either electronic or written comments on the draft guidance by April 29, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may

not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions".

Instructions: All submissions received must include the Docket No. FDA-2014-D-1584 for "Same Surgical Procedure Exception: Questions and Answers Regarding the Scope of the Exception; Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions", publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION”. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential”. Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:
<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lori J. Churchyard, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of October 23, 2014 (79 FR 63348), FDA announced the availability of a draft document entitled “Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception; Draft Guidance for Industry” dated October 2014. The draft guidance is intended for tissue establishments and health care professionals and discusses one of the exceptions for establishments from certain regulatory requirements. Interested persons were originally given until December 22, 2014, to comment on the draft guidance.

Elsewhere in this issue of the Federal Register, FDA is announcing four other related documents. In a separate document, FDA is announcing a public hearing entitled “Draft Guidances Relating to the Regulation of Human Cells, Tissues, or Cellular or Tissue-Based Products; Public Hearing; Request for Comments” (part 15 hearing) to be held on April 13, 2016, to provide stakeholders with the opportunity to discuss FDA’s policy on regulation of human cells, tissues, and cellular and tissue-based products (HCT/Ps) related to the four draft guidances on the following topics: Homologous use, same surgical procedure exception, minimal manipulation, and adipose tissue.

In a separate document, FDA is announcing the availability of a draft document entitled “Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and FDA Staff.”

In separate documents, FDA is also reopening the comment periods to FDA's public dockets on the previously issued draft guidance documents on the following topics related to HCT/Ps: Minimal manipulation (Docket No. FDA-2014-D-1696) and adipose tissue (Docket No. FDA-2014-D-1856).

II. Reopening of Comment Period

Following publication of the October 23, 2014, notice of availability, FDA received a request to allow interested persons additional time to comment. In conjunction with the part 15 hearing and announcement of availability of the homologous use draft guidance, FDA is reopening the comment period to allow potential respondents to thoroughly evaluate and address pertinent issues. The same surgical procedure exception draft guidance and other related guidances (homologous use, minimal manipulation, adipose tissue) all deal with the interpretation of the regulations under 21 CFR part 1271 that will be addressed as part of the part 15 hearing.

Dated: October 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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